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U.S. COURT OF APPEALS

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

PRISCILLA JEANNE COLLETTE, as the personal representative of the estate of Raymond J. Collette, Plaintiff-Appellant, v. WYETH PHARMACEUTICALS, INC.; et al., Defendants-Appellees.	No. 20-16406 D.C. No. 3:16-cv-01034-JD MEMORANDUM*

Appeal from the United States District Court
for the Northern District of California
James Donato, District Judge, Presiding

Argued and Submitted June 9, 2021
Seattle, Washington

Before: W. FLETCHER, WATFORD, and COLLINS, Circuit Judges.
Concurrence by Judge COLLINS

Raymond Collette appeals from the district court's dismissal of his claims alleging that defendants' conduct led to the injuries he suffered after taking amiodarone. We affirm.

* This disposition is not appropriate for publication and is not precedent except as provided by Ninth Circuit Rule 36-3.

1. The district court properly dismissed the medication guide claims for failure to satisfy the pleading standard of Federal Rule of Civil Procedure 8. Collette fails to allege facts plausibly suggesting that defendants' wrongdoing led to Collette's not receiving medication guides with the amiodarone prescriptions he filled. Notably, he does not allege that defendants failed to meet their obligations under the federal regulations that impose the medication guide requirement. Although Collette pleads that defendants did not provide the guides to him directly and did not provide the guides to the distributors or pharmacies from which he received the medication, he never alleges that defendants failed to "provid[e] the means to produce Medication Guides," which would also have satisfied their regulatory obligation. *See* 21 C.F.R. § 208.24(b)(2). Absent factual allegations plausibly suggesting that defendants violated their federal regulatory obligations, Collette has not satisfied the pleading requirements of Rule 8 as interpreted in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009).

2. The district court also properly dismissed Collette's off-label marketing claims. Under the heightened pleading standards of Federal Rule of Civil Procedure 9(b), Collette was required to "state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b), which requires specifying "the who, what, when, where, and how of the misconduct charged." *Kearns v. Ford Motor Co.*,

567 F.3d 1120, 1124 (9th Cir. 2009) (quotation marks omitted). Collette's allegations against the generic defendants are far too general to meet these requirements, as he offers no factual details explaining how the generic defendants sought to "capitalize" on Wyeth's off-label marketing campaign, and he fails to attribute specific acts of wrongdoing to specific defendants.

The allegations against Wyeth include somewhat more detail about Wyeth's promotional activities, but Collette falls short of the Rule 9(b) requirements with regard to these allegations as well. Although Collette alleges that his physicians viewed information about amiodarone on third-party platforms and that this information was misleading because of Wyeth's promotional activities, he fails to identify specific statements that Wyeth made, which statements Collette's doctors viewed, or how those statements influenced the doctors' decision to prescribe Collette amiodarone. That is insufficient to provide defendants with adequate notice to allow them to defend against the charges, and thus fails to meet Rule 9(b)'s pleading requirements. *See Kearns*, 567 F.3d at 1125–26.

3. Finally, the district court properly dismissed Collette's failure-to-report-adverse-events claim under Federal Rule of Civil Procedure 41(b). In its June 2019 order, the district court clearly stated that Collette's authorization to amend was "limited to claims based on his off-label marketing allegations only" and that addition of new claims would result in dismissal under Rule 41(b). The district

court did not abuse its discretion by following through on this promise when Collette failed to comply with the court's instructions. *See Pagtalunan v. Galaza*, 291 F.3d 639, 642 (9th Cir. 2002).

AFFIRMED.

Collette v. Wyeth Pharm., Inc., No. 20-16406

COLLINS, Circuit Judge, concurring in the judgment:

I agree with the majority that the district court properly dismissed the claims that were asserted below by Plaintiff Raymond Collette,[1] but my reasoning differs in some respects from the majority's. I therefore concur only in the judgment.

1. I agree with the majority that the medication-guide claims fail, but I would rely on a different ground.

The majority holds that Collette's complaint did not adequately allege that the reason Collette did not receive the required medication guide concerning amiodarone from the relevant pharmacies was that Defendants failed to comply with their federal regulatory obligations. In reaching that conclusion, the majority notes that, while Collette *did* allege that Defendants did not supply the guide to him or to his pharmacies, Collette did not specifically allege that Defendants failed to provide the pharmacies with *the means* to produce the guide. *See* Mem. Dispo. at 2 (citing 21 C.F.R. § 208.24(b)(2)). Because he did not expressly foreclose this alternative, the majority concludes, Collette did not sufficiently allege that Defendants actually violated the regulation. *Id*. The district court, however, did not rely on this particular omission below, and Defendants do not mention it in their brief on appeal. It seems to me improper to uphold a dismissal of a claim

[1] After Collette's death, his wife was substituted as Plaintiff-Appellant in this court.

with prejudice based on a pleading defect that was not relied upon by the district court or the defendants, and that the plaintiff has had no opportunity to correct. Indeed, Collette's opening brief characterizes the existing complaint as *already* alleging that "Defendants did not provide sufficient Medication Guides (*or the means of producing them*) to the distributer or to the pharmacies where Mr. Collette filled his prescriptions" (emphasis added). At the very least, that statement confirms that, if given leave to replead, Collette could amend the complaint to correct the particular newly-discovered defect identified by the majority.

I also do not agree with the district court's given reasons for concluding that the complaint failed to allege sufficient facts to satisfy the pleading standards set forth in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). The district court stated that the allegations concerning the medication-guide claims were "too cursory and vague," but the only example of an "additional factual detail" that the court said should have been included was the identity of "the pharmacy at which [Collette] filled his prescription." I disagree with the district court's conclusion that, merely by omitting the names of the particular pharmacies that filled his prescriptions, Collette thereby failed to allege enough facts to establish that Defendants violated the medication-guide regulation. To be sure, I cannot fathom why Collette did not include this detail in his second amended complaint when the district court in a

prior order had specifically asked for it to be included.[2] But that does not mean that this failure amounts to a violation of the pleading standards of Federal Rule of Civil Procedure 8. Even absent this detail, Collette's complaint sufficiently alleged that Defendants simply failed to supply the medication guides to the relevant distributor and pharmacies and that this failure was the reason why Collette did not receive those guides when he filled his prescriptions. That is enough to raise a plausible inference that Defendants violated the regulation, *Iqbal*, 556 U.S. at 678–80, and to give Defendants "'fair notice of what the . . . claim is and the grounds upon which it rests,'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (alteration in original) (citation omitted).

I would instead affirm the dismissal of these claims on the ground that, as the district court alternatively held, they are preempted. *See McDaniel v. Upsher-Smith Labs, Inc.*, 893 F.3d 941, 944 (6th Cir. 2018). Because these claims rest solely upon Defendants' alleged failure to provide the medication guide to pharmacists to give to Collette as required by federal regulations, they are preempted by federal law under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Collette argues that the claims do not "exist solely by virtue of the [federal medication-guide] requirements," *id*. at 353, but rather rely on parallel

[2] It is particularly puzzling given that, at oral argument, Collette's counsel asserted that the relevant pharmacies were identified during the parties' exchange of initial disclosures required under the applicable rules.

state-law duties, *see McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040–41 (9th Cir. 2015). This contention is untenable in light of well-settled California law holding that a drug manufacturer's "duty to warn of risks associated with [the drug's] usage runs to the physician, *not the patient*." *Conte v. Wyeth, Inc.*, 85 Cal. Rptr. 3d 299, 308 n.5 (Cal. Ct. App. 2008) (emphasis added); *see also Bigler-Engler v. Breg, Inc.*, 213 Cal. Rptr. 3d 82, 119 (Cal. Ct. App. 2017) ("'In the case of prescription drugs and implants, the physician stands in the shoes of the "ordinary user" because it is through the physician that a patient learns of the properties and proper use of the drug or implant. Thus, the duty to warn in these cases runs to the physician, not the patient.'" (citation and emphasis omitted)). Because the relevant state-law duty does not parallel the federal regulatory obligation to provide a medication guide for delivery to the consumer, Collette's medication-guide claims reflect an attempt to use state common law to enforce an obligation that exists solely by virtue of federal law. Under *Buckman*, such a claim is preempted, as the district court correctly held.

2. I agree with the majority that the district court properly dismissed Collette's off-labeling marketing claims as inadequately pleaded, but again my reasoning differs somewhat from the majority's.

Collette's opening brief does not contest that Federal Rule of Civil Procedure 9(b) applies to these claims, and I agree that Collette's operative

complaint fell short of the standards set by that rule. But contrary to what the majority suggests, *see* Mem. Dispo. at 3, I think that the complaint adequately alleges that Collette's physician relied on third-party sources incorrectly stating that treatment of atrial fibrillation is an indicated use of amiodarone. But the claims nonetheless fail, in my view, because the complaint does not allege sufficient facts to establish that *Defendants* are responsible for these third-party statements. The complaint alleges that Wyeth engaged in certain practices concerning off-label promotion of amiodarone at a conference in 1998; that Wyeth received warning letters about off-label promotion of amiodarone from the FDA in 1989, 1992, and 1998; and that a 2011 task force of physicians promoted off-label use of the drug while having financial connections to Wyeth and other unspecified entities "that would profit from off-label use of [a]miodarone." Beyond that, however, the complaint's allegations concerning an alleged campaign to promote off-label uses are entirely conclusory. These meager allegations are not enough, under Rule 9(b), to establish that Defendants are responsible for the statements in third-party materials that Collette's doctor allegedly read in late 2011.

3. I agree with the majority that the district court properly dismissed the failure-to-report-adverse-events claim, but I disagree with its conclusion that the dismissal may be upheld under Federal Rule of Civil Procedure 41(b) on the ground that Collette failed to comply with a court order. We have stated that

dismissal under Rule 41(b) "is a harsh penalty and, therefore, it should only be imposed in extreme circumstances." *See Ferdik v. Bonzelet*, 963 F.2d 1258, 1260 (9th Cir. 1992). In my view, no such circumstances exist here. The order that Collette allegedly violated was the district court's order that granted him leave to file a third amended complaint containing "claims based on his off-label marketing allegations only." Although Collette may have violated the spirit of the order, and the district court's intention in issuing that order, he did not violate its literal terms. The allegations of fraudulent off-label marketing in Collette's second amended complaint *already included* failure-to-report allegations, and by splitting those allegations off into a freestanding failure-to-warn claim, Collette thereby literally alleged a claim that was "based on his off-label marketing allegations." Accordingly, the dismissal of these claims cannot be sustained under Rule 41(b).

I agree, however, with the district court's alternative conclusion that this claim was inadequately pleaded. The general allegations that Defendants "failed to report thousands of serious adverse medical events in their exclusive possession to the FDA, health care professionals, and consumers" lack any meaningful detail about the nature of the adverse events that Defendants allegedly withheld. While Collette did not have to allege the details of all of these thousands of alleged events, he had to provide at least some overall description of them that would be sufficient to raise a plausible inference that, "'if [Defendants] had properly

reported the adverse events to the FDA as required under federal law, that information would have reached [his] doctors in time to prevent his injuries.'" *Coleman v. Medtronic, Inc.*, 167 Cal. Rptr. 3d 300, 312 (Cal. Ct. App. 2014) (citation omitted). As the district court correctly held, Collette failed to do so.

For the foregoing reasons, I concur in the judgment.